

Applicants maintain that claims 1-5, 7-9, 36, 38, 39 and 51 are indeed patentable over the art for reasons of record. However, in an effort to advance prosecution, these claims have been canceled. Cancellation is without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more related applications toward the canceled claims.

New claims 52 and 53 have been added. These claims correspond to allowed claim 29, with the amount and type of metabolizable oil, as well as the amount and type of emulsifying agent, specified. Thus, these claims are also patentable over the art.

In particular, the metabolizable oil is specified as squalene, present in an amount of 5% by volume. The emulsifying agent is specified as polyoxyethylthylenesorbitan monooleate and/or sorbitan trioleate, the generic names for Tween 80 and Span 85, respectively (see the Sigma catalogue excerpts accompanying this response), in a total amount of 1% by weight. Support for these new claims can be found at, e.g., page 56, lines 25-26; and page 58, line 16. Accordingly, no new matter has been added by way of the new claims.

CONCLUSION


In view of the foregoing, applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

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08/418,870; 0085.006; 2302-0085.04

Currently Pending Claims

(08/418,870; 0085.006; 2302-0085.04)

29. (Four times amended) A method of stimulating an immune response in a host animal comprising:

administering an antigen to said animal in the presence of an immunostimulating amount of an adjuvant composition consisting essentially of:

(1) a metabolizable oil, wherein the oil is present in an amount of 0.5% to 20% of the total volume and

(2) an emulsifying agent, wherein the emulsifying agent is 0.01% to 2.5% by weight (w/w), and wherein said oil and said emulsifying agent are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are about 100 nm to less than 500 nm in diameter and wherein said composition exists in the absence of any polyoxypropylene-polyoxyethylene block copolymer and in the absence of any muramyl peptide, and further wherein said adjuvant composition is capable of increasing the immune response to said antigen.

40. The method of Claim 29, wherein said oil is an animal oil.

41. The method of Claim 40, wherein said oil is an unsaturated hydrocarbon.

42. The method of Claim 29, wherein said oil is a terpenoid.

43. The method of Claim 29, wherein said oil is a vegetable oil.

44. The method of Claim 29, wherein said emulsifying agent comprises a non-ionic detergent.

45. The method of Claim 29, wherein said emulsifying agent comprises a polyoxyethylene sorbitan mono-, di-, or triester or a sorbitan mono-, di-, or triester.

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46. The method of Claim 45, wherein said adjuvant composition comprises .02 to 2.5 % by weight of said emulsifying agent.

47. The method of Claim 29 wherein the oil is present in an amount of 1% to 12% of the total volume and the emulsifying agent is 0.05% to 1% by weight (w/w).

48. The method of Claim 29 wherein the oil is present in an amount of 1% to 4% of the total volume and the emulsifying agent is 0.01% to 0.05% by weight (w/w).

49. The method of claim 29 wherein said emulsifying agent comprises a polyoxyethylene sorbitan mono-, di-, or triester and a sorbitan mono-, di-, or triester.

50. The method of claim 49 wherein said oil comprises squalene.

52. A method of stimulating an immune response in a host animal comprising:
administering an antigen to said animal in the presence of an immunostimulating amount of an adjuvant composition consisting essentially of:

(1) 5% by volume of squalene; and

(2) one or more emulsifying agents selected from the group consisting of polyoxyelthylenesorbitan monooleate and sorbitan trioleate, wherein the total amount of emulsifying agent(s) present is 1% by weight (w/w); wherein said squalene and said emulsifying agent(s) are present in the form of an oil-in-water emulsion having oil droplets substantially all of which are about 100 nm to less than 500 nm in diameter and wherein said composition exists in the absence of any polyoxypropylene-polyoxyethylene block copolymer and in the absence of any muramyl peptide, and further wherein said adjuvant composition is capable of increasing the immune response to said antigen.

53. The method of claim 52, wherein the one or more emulsifying agents are polyoxyelthylenesorbitan monooleate and sorbitan trioleate and the total amount of

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polyoxyelthylenesorbitan monooleate and sorbitan trioleate present is 1% by weight (w/w).